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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/289,321	04/09/1999	WILLIAM W. BACHOVCHIN	19644-010	8452

7590

05/03/2002

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EXAMINER

LUKTON, DAVID

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 05/03/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/289,321

Applicant(s)
Bachovkin

Examiner
David Lukton

Art Unit
1653



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 13, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 73 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Pursuant to the directives of paper No. 18 (filed 2/13/02), claim 1 has been amended, claims 17, 35, 39, 71, 72 cancelled and claim 73 added. Claims 1 and 73 are pending.

Applicants' arguments filed 2/13/02 have been considered and found not persuasive.

*

This application contains sequence disclosures that are encompassed by the definitions for amino acid sequences set forth in 37 CFR 1.821. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 with regard to the sequence disclosures.

On page 3 (page 3 of 17 pages) of paper No. 18, there is a statement that a paper copy of the sequence listing has been provided. However, no such paper copy is present. The paper copy should include (at least) SEQ ID NOS: 6-9. In addition, a second CRF has not been received, despite the fact that applicants have stated that they have submitted one. The absence of a paper copy of the sequence listing appears to be an unintended omission by applicants. As for the CRF listing, it is impossible to determine who might be responsible for the absence of entry into the computer database. However, rather than trying to assign blame, it is suggested that applicants simply resubmit the CRF listing, as this will facilitate prosecution. Computer diskettes should be sent to one of the addresses on the attached sheet.

Applicant is given the time period set in this letter within which to comply with the sequence rules, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period.

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 73 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 73 is drawn to an oligomer in which there are a number of units each of which bears a boronate group. The numerical range of such units is 3-200. However, it does not appear that there is descriptive support for this range. Applicants are requested to point out the page and line number for support.

*

Claims 1 and 73 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- In claims 1 and 73, the phrase "capable of forming" renders the claim indefinite as to whether the forming takes place. Applicants have argued that one of ordinary skill could determine what this means. One of the issues here is what happens if, for example, an atom is "capable of forming a double bond with nitrogen", but for one reason or other does not form the double bond. What would this mean, chemically and physically?
- The claims recite that "L" can have a weight of 2000 D, yet have a "length" of only 20 Å. How is this possible? It would be helpful if applicants could provide an example of this.
- Claim 1 recites each of the following:

"weight ranging between about 1100 D and about 2000 D"
"having a span ranging from about 20 Å to about 300 Å"

However, the term "about" in each case introduces indefiniteness as to the upper and lower limits. Is the upper limit of the weight 2000 Daltons, or is the upper limit more than 2000 Daltons? It is suggested that the term "about" be deleted in these cases where a range is cited. The same deficiency afflicts claim 73.

- In claim 73, there is a minor typographical error. The compound consists of three separate structures, one of which is in brackets and is taken "n" times. In this structure, the group "[J]" is present. Adjacent to "[J]" is the integer variable "p". However, this integer variable "p" should be on the right-hand side of "[J]", rather than the left-hand side, for consistency.

*

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

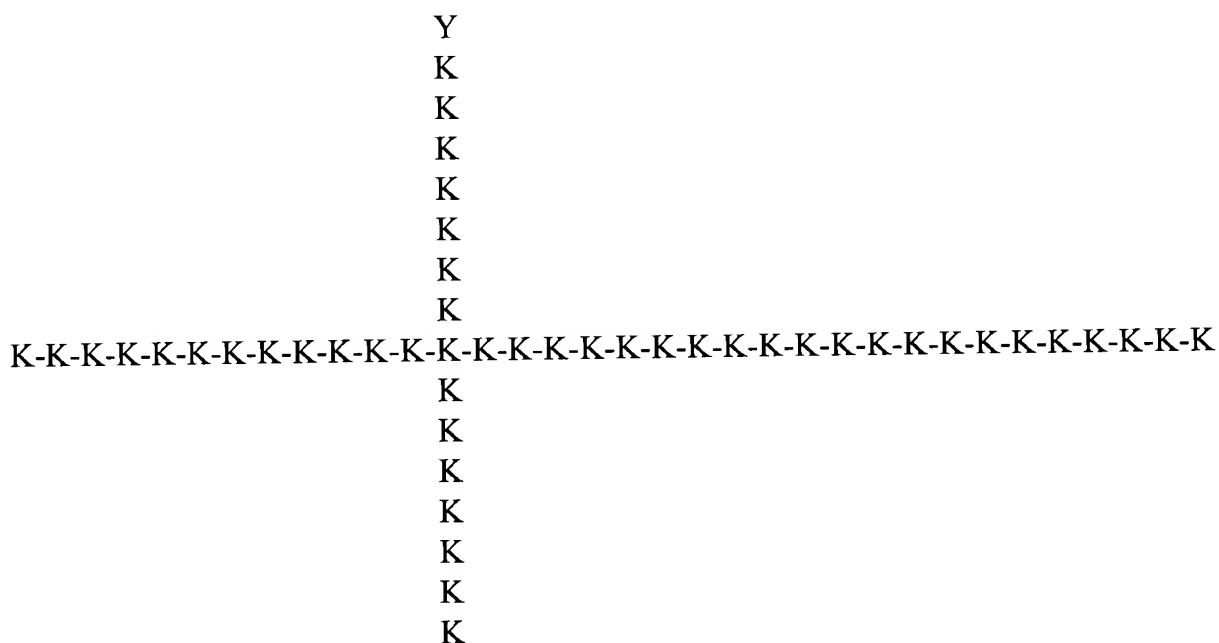
Claims 1 and 73 are rejected under 35 U.S.C. §103 as being unpatentable over Bachovchin (USP 5,776,902).

As indicated previously, Bachovchin discloses (e.g., col 50, line 5+) peptidomimetics which contain one or more moieties that have phenylboronate sidechains.

Applicants have traversed by arguing first that the boron-containing group in USP '902 represents a phosphate group, whereas in the instant case the boron-containing group represents a carboxylic acid group. However, the relevance of this is not evident. What matters is what the respective structures are, not what a given functional group might be representing or mimicking. Next applicants argue that a chemist considering the '902 patent would not be motivated to replace a carboxylic acid group with a boronate ester group. However, no such replacement is required. The reference clearly and unequivocally teaches the presence of one or more phenylboronate groups. Next, applicants argue that, in the instant case, the boronate group must be located at the C-terminus, whereas in the '902 patent, the boronate groups can be located at internal positions. The examiner will stipulate that in the '902 patent, the boronate groups can be located at internal positions. However, applicants are mistaken about what the instant claims require. First, in order to have a "C-terminus", there must be a recognizable peptide to begin with. The term "C-

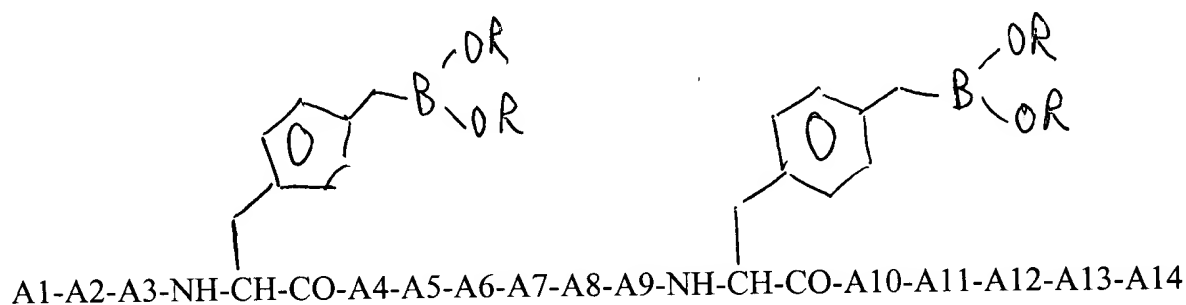
terminus" is recognized for the case when one has a chain of alpha-amino acids bonded together in linear fashion, and there is no branching. However, it appears that the claims do not require the presence of even one *alpha*-amino acid, or for that matter a *beta*-amino acid, or a *gamma*-amino acid, and certainly neither of the claims requires the presence of multiple amino acids. Thus, there is in fact no "C-terminus". However, the argument can be taken a step further. Suppose, for the sake of argument, that the claim did actually require the presence of several amino acids. The fact would still remain that there are no limits on the dimensions of "L". It is true that the claim recites that "L" must have a span of 20 - 300 Angstroms. However, this is not particularly meaningful, in and of itself. Molecules are three-dimensional entities. To take one example, suppose that one has a pipe (e.g., for carrying water) which has a diameter of 2 inches, and a length of 500 feet. If one is permitted to describe this pipe by pretending that it is a two-dimensional object, one would then have the choice of saying either that the pipe "spans" two inches, or that the pipe "spans" 500 feet. In the case of molecules, the situation is more complicated, because most molecules are not rigid structures (polymers which include cross links are a separate issue). Consider, for example, a water-soluble protein for which the structure has been well-studied in both the crystal state and solution. Suppose, for example that a given protein adopts a tertiary structure such that it would fill a sphere (as opposed to an "oblong" shape). In that case, one could perhaps say that the "length" of

the molecule is about equal to the diameter of that sphere. But what happens if the molecule is placed in 8 molar urea? The "span" would then be (according to one interpretation) the length of the molecule, and as such, the span in the latter case would be far greater than in the former case. Next, consider the case of a peptide that has a single branch point. Consider the following structure, wherein "K" represents a lysine residue, and "Y" represents tyrosine:



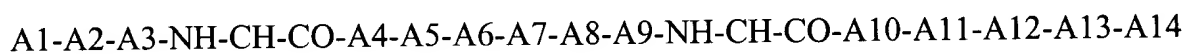
In this case, is the "span" measured vertically, or horizontally? Or what about 13 (lysines) across (from the left) and 7 "up"...? Next consider the tyrosine (depicted with the letter "Y"). The question is, is this tyrosine at a "C-terminus", or is it at an internal position? The fact is that it could be either; it all depends on one's definitions. Next, consider the

following:



In the foregoing, the "A" groups can be amino acids. In this case, applicants might be inclined to argue that the boronate groups are in internal positions. However, that is not necessarily the case. The fact is that in the instant claims, the "L" group is not constrained structurally. In particular, **there is no prohibition on "L" being branched.**

Thus, in this example, the "L" group can simply correspond to the following:



In this example, "L" would have two branch points. But there is nothing in the claims to preclude "L" from having 100 branch points.

Applicants final ground of traversal is that the instant claims are drawn to peptidomimetics. First, there is no such limitation in the claims, but even if there were, there would be no distinction between a single "peptidomimetic", and an oligomer of a "peptidomimetic".

The rejection is maintained.

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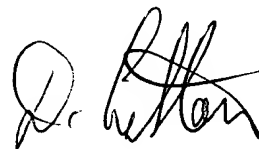
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Applicants have argued that the references were submitted in application 08/837,305. However, the references are not present in the file. Accordingly, no references were considered beyond those which were already indicated as having been considered (in the previous Office action).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



DAVID LUKTON
PATENT EXAMINER
GROUP 1800

A reply to a notice to comply with the sequence rules should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office. (The disks are being irradiated by electron bombardment and are showing up melted, unreadable, and or crazed).

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